

510(k) Summary

JUN - 4 2008

General Provisions	Submitter Name:	Bard Access Systems, Inc. (BAS) [Wholly owned subsidiary of C.R. Bard, Inc.]
	Address:	605 N 5600 W Salt Lake City, UT 84116
	Telephone Number:	(801) 595-0700 ext. 7105
	Fax Number:	(801) 595-5425
	Contact Person:	Ji Hyun Kim
	Date of Preparation:	May 30, 2008
	Registration Number:	3006260740 BAS 2212754 C. R. Bard
Subject Device	Trade Name:	PowerPort™ Implanted Port with Groshong® Catheter
	Common/Usual Name:	Implanted Infusion Port & Catheter
	Classification Name:	80 LJT – Subcutaneous, Implanted, Intravascular Infusion Port & Catheter
Predicate Devices	Trade Name:	PowerPort™ Implanted Titanium Port
	Common/Usual Name:	Implanted Infusion Port & Catheter
	Classification Name:	80 LJT – Subcutaneous, Implanted, Intravascular Infusion Port & Catheter
	Premarket Notification:	K060812, clearance date July 14, 2006
Classification	Class II 21 CFR §880.5965 General Hospital	
Performance Standards	Performance standards have not been established by FDA under section 514 of the Federal Food, Drug and Cosmetic Act.	
Intended Use	PowerPort™ devices are totally implanted vascular access devices designed to provide long-term, repeated access to the vascular system.	
Indications for Use	The PowerPort™ implanted port is indicated for patient therapies requiring repeated access to the vascular system. The port system can be used for infusion of medication, I.V. fluids, parenteral nutrition solutions, blood products, and for the withdrawal of blood samples. When used with a PowerLoc™ safety infusion set, the PowerPort™ device is indicated for power injection of contrast media. For power injection of contrast media, the maximum recommended infusion rate is 5 ml/s.	

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**Device
Description**

The subject PowerPort™ implanted port with Groshong™ catheter is a member of the PowerPort™ series of power injectable implanted ports. The subject device consists of a titanium port and silicone Groshong® tipped and valved catheter that is attached to the port with a cathlock compression fitting. The subject port is distinguishable as a member of BAS's power injectable port series by the triangular body shape, unique purple coloring, and three palpation bumps on the septum.

PowerPort™ implanted ports can be used for routine vascular access using a non-coring access needle. However, for power injection procedures, PowerPort™ ports must be accessed with a Bard PowerLoc™ safety infusion set to create a power injectable system.

**Technological
Characteristics**

Technological characteristics of the subject PowerPort™ implanted port with Groshong™ catheter are equivalent to those of the Bard Access Systems predicate PowerPort™ Implanted Titanium Port [K060812].

**Safety &
Performance
Tests**

No performance standards have been established under Section 514 of the Food, Drug and Cosmetic Act for this device. However, design verification testing was performed according to protocols based on the recommendations/requirements of applicable FDA guidance and FDA recognized international standards. Verification testing, determined to be applicable to the safety and efficacy of the device, was shown to meet predetermined acceptance criteria listed therein.

Risk management, including a failure modes and effects analysis (FMEA), of the subject device was conducted in accordance with an internal protocol based on ISO 14971:2007, *Medical Devices – Application of Risk Management to Medical Devices (General)*. The analysis did not identify any new types of safety or efficacy questions for the subject PowerPort™ implanted port with Groshong™ catheter.

**Summary of
Substantial
Equivalence**

Based on the indications for use, technological characteristics, and safety and performance testing, the subject PowerPort™ implanted port with Groshong™ catheter meets the minimum requirements that are considered adequate for its intended use and is substantially equivalent in design, materials, sterilization, principles of operation and indications for use to current commercially available implanted ports cited as predicates.

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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Ji-Hyun Kim
Regulatory Affairs Manager
C.R. Bard, Incorporated
Bard Access Systems, Incorporated
605 North 5600 West
Salt Lake City, Utah 84116

Re: K081311
Trade/Device Name: PowerPort™ Implanted Port with Groshong™ Catheter
Regulation Number: 21 CFR 880.5965
Regulation Name: Subcutaneous, Implanted, Intravascular Infusion Port and Catheter
Regulatory Class: II
Product Code: LJT
Dated: May 8, 2008
Received: May 9, 2008

Dear Ms. Kim:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Chiu Lin, Ph.D.

Director

Division of Anesthesiology, General Hospital,

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known):

K081311

Device Name:

PowerPort™ Implanted Port
with Groshong™ Catheter

Indications for Use:

The PowerPort™ implanted port is indicated for patient therapies requiring repeated access to the vascular system. The port system can be used for infusion of medication, I.V. fluids, parenteral nutrition solutions, blood products, and for the withdrawal of blood samples. When used with a PowerLoc™ safety infusion set, the PowerPort™ device is indicated for power injection of contrast media. For power injection of contrast media, the maximum recommended infusion rate is 5 ml/s.

Prescription Use ☒
(Part 21 CFR §801 Subpart D)

AND/OR

Over-The-Counter Use ☐
(21 CFR §801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Anthony D. Watson
(Division Sign-Off)

Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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